MAR 1 4 2013

510(k) Summary

Device Trade Name: Paragon™ Hip System

Manufacturer: Global Manufacturing Technology
Unit 7, 12 Boden Road
Seven Hills, NSW 2147 AUSTRALIA

Prepared by: Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
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Date Prepared: February 5, 2013

Classifications: 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.

Class: II

Product Codes: LZO, MEH

Indications for Use:
The Paragon™ Hip System is intended for use as the femoral component of a total hip replacement or partial hip replacement. This femoral hip stem is intended for uncemented fixation and single use implantation. This prosthesis may be used for the following conditions, as appropriate:

1. Degenerative osteoarthritis of the hip.
2. Inflammatory arthritis of the hip.
3. Secondary arthritis of the hip, such as may follow trauma (e.g. fracture of the femoral neck, or fracture and/or dislocation of the hip or acetabulum), or congenital conditions (e.g. developmental dysplasia of the hip).
4. Displaced intracapsular femoral neck fractures where there is a high risk of non-union or avascular necrosis and bone collapse.
5. Avascular Necrosis of the femoral head.
6. Revision of a failed femoral component from previous hip surgery e.g. internal fixation device from previous osteotomy, fracture treatment or hemi-arthroplasty.

Device Description:
The Paragon™ Hip System is to be used in conjunction with a compatible femoral head and acetabular component as part of a total hip arthroplasty, or as the femoral stem in a hemi-arthroplasty.

The body of the Paragon™ Hip System tapers proximal to distal in the lateral and frontal planes, and lateral to medial in the sagittal plane resulting in a bi-planar wedge geometry that is conducive to axial and rotational stability.

The Paragon™ Hip System is manufactured from titanium alloy (Ti6Al4V ELI per ASTM F136) and Hydroxyapatite (HA) (ISO 13779-1 for the HA powder and ISO 13779-2 for the coating).

Predicate Devices:
Comparative information presented in the 510(k) supports the substantial equivalence of the Paragon™ Hip System to the following predicate devices: DePuy Orthopaedics Corail Hip (K042992), Smith & Nephew's Anthology Hip (K052792), and Consensus CS2™ Hip System (K122512).

Substantial Equivalence:
The components of the Paragon™ Hip System are substantially equivalent to the identified predicates with respect to indications for use, geometry, available sizes, materials, performance and function.

Preclinical Testing:
The preclinical tests performed on the Paragon™ Hip System include Range of Motion, Stem Fatigue Testing, Neck Fatigue Testing, Burst Strength Testing when coupled with ceramic femoral heads, and characterization of the stem's HA coating. The results support the substantial equivalence of the Paragon™ Hip System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

March 14, 2013

Global Manufacturing Technology
% Musculoskeletal Clinical Regulatory Advisers, LLC
Ms. Hollace S. Rhodes
Director, Orthopedic Regulatory Affairs
1331 H Street, Northwest, 12th Floor
Washington, DC 20005

Re: K123782
Trade/Device Name: Paragon™ Hip System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH
Dated: February 7, 2013
Received: February 11, 2013

Dear Ms. Rhodes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K123782

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Prescription Use ___√___ (Part 29 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___no___ (29 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices